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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/914,705	YAMADA ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *5-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,15 and 16* is/are rejected.

7)☒ Claim(s) *15-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 1-24-2007 are acknowledged. Claims 1, 3, 4 and 15-16 been amended. Claim 17 has been canceled. Claims 1-16 are pending. Claims 5-14 remain withdrawn from consideration as being drawn to non-elected inventions. Claims 1-4 and 15-16 are currently under examination.

Claim Rejections Withdrawn

The rejection of claim 4 under 35 U.S.C. 112, second paragraph for lacking antecedent basis for the limitation "prepared from a medicinal plant" in line 1 is withdrawn in light of the amendment thereto.

The new matter rejection of claim 17 under 35 U.S.C. 112, first paragraph, based on the limitation "consisting essentially of a purified or synthesized hydroxyl unsaturated fatty acid as a sole active ingredient..." is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claims 1-3 and 15-16 under 35 U.S.C. 102(a) as being anticipated by Lederer et al. (J. Agric. Food Chem. 1999, Vol. 47, pages 4611 –4620) is withdrawn in light of the amendment thereto. The cancellation of claim 17 has rendered the rejection of that claim moot. It should be noted that this rejected is withdrawn due to a limitation that is deemed to constitute new matter. As such this rejection may be applied again depending on the outcome of the aforementioned new matter issue.

New Claim Objections

Claims 16-17 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Said claims are all drawn to the same compositions. The recitation of a property possessed by the composition does not constitute a limitation.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3 and 15-16 under 35 U.S.C. 102(a) as being anticipated by Quinton et al. (Tetrahedron Letters, 1991, Vol. 32, No. 37, pages 4909-4912) is maintained for reasons of record. The cancellation of claim 17 has rendered the rejection of that claim moot.

Applicant argues:

1. Quinton discloses the claimed 18 carbon hydroxyl unsaturated fatty acids in solvents that are unacceptable for administration to a subject and hence do not meet the limitation of being a

"pharmaceutical composition" as required by the amended claims. Nor do they disclose the recited level of purity.

2. Quinton does not disclose the experimental systems are being used to test the biological activities of the claimed compositions.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, Quinton et al. disclose that the biological activities of the disclosed compositions are being tested (see page 4912) which would necessarily require them to be acceptable for administration to a subject.

With regard to Point 2, the specific tests used are not relevant to discussion at hand. Testing of the biological activity of a compound requires the application of the compound to a living organism. This application, regardless of the specific test, would necessarily require that said compound be in a biologically (i.e. pharmaceutically) acceptable form.

Moreover, MPEP 2112 states:

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on *prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Purification does not constitute an unobvious difference.

As outlined previously, Quinton et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3. The use of the descriptive term "pharmaceutical composition" is deemed to be an intended use and hence does not constitute a claim limitation. Moreover, Quinton et al. disclose that the biological activities of the disclosed compositions are being tested (see page 4912) which would necessarily require them to be acceptable for administration to a subject. Consequently, Quinton anticipates all the limitations of the rejected claims.

The rejections of claims 1-4 and 15-16 under 35 U.S.C. 102(b) as being anticipated by Miyaichi et al. (Natural Medicines 1995, Vol. 49 No. 1, pages 24-28) is maintained for reasons of record.

Applicant argues:

1. Miyaichi discloses the claimed 18 carbon hydroxyl unsaturated fatty acids in solvents that are unacceptable for administration to a subject and hence do not meet the limitation of being a "pharmaceutical composition" as required by the amended claims.
2. Miyaichi does not disclose the requisite purity of the disclosed compound.

Applicant's arguments have been fully considered and deemed non-persuasive.

As acknowledged by Applicant, Miyaichi et al. disclose the claimed 18 carbon hydroxyl unsaturated fatty acid as one of 21 compounds in the herb "Sanleg". As said herb comprises the claimed compound and is acceptable for administration to a subject. Moreover, MPEP 2112 states:

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on *prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Purification does not constitute an unobvious difference.

As outlined previously, Miyaichi et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC report). The use of the descriptive term "pharmaceutical composition" is deemed to be an intended use and hence does not constitute a claim limitation. Moreover, as acknowledged by Applicant, Miyaichi et al. disclose the claimed 18 carbon hydroxyl unsaturated fatty acid as one of 21 compounds in the herb "Sanleg". As said herb comprises the claimed compound and is acceptable for administration to a subject, Miyaichi et al. anticipates all the limitations of the rejected claims.

The rejection of claims 1-4 and 15-16 under 35 U.S.C. 102(b) as being anticipated by Hamberg et al. (Plant Physiology, 1996, Vol. 110, pages 807-815) is maintained for reasons of record. The cancellation of claim 17 has rendered the rejection of that claim moot.

Applicant argues:

1. Hamberg discloses the claimed 18 carbon hydroxyl unsaturated fatty acids in solvents that are unacceptable for administration to a subject and hence do not meet the limitation of being a "pharmaceutical composition" as required by the amended claims nor do they disclose the requisite purity of the disclosed compound.

Applicant's arguments have been fully considered and deemed non-persuasive.

Hamberg et al. disclose the claimed 18 carbon hydroxyl unsaturated fatty acid as one of compounds of oat seeds. As said seed comprises the claimed compound and is acceptable for administration to a subject. . Moreover, MPEP 2112 states:

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on *prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Purification does not constitute an unobvious difference.

As outlined previously, Hamberg et al. disclose an 18-carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report) wherein said fatty acid was isolated from *Avena sativa* seed homogenates. The use of the descriptive term "pharmaceutical composition" is deemed to be an intended use and hence does not constitute a claim limitation. Moreover, Hamberg et al. disclose the claimed 18 carbon hydroxyl unsaturated

fatty acid as one of compounds of oat seeds. As said seed comprises the claimed compound and is acceptable for administration to a subject, Hamberg et al. anticipates all the limitations of the rejected claims.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 1 and 15-16 to recite "wherein the purity of the hydroxyl unsaturated fatty acid is 95% or higher." This phrase does not appear in the specification, or original claims as filed. The portions of the specification cited by Applicant disclose the recited level of purity only in regard to a 9, 12, 13-trihydroxy-10E-octadecenoic acid. This disclosure does not provide support for the full breadth of the rejected claims. Therefore this limitation is new matter.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederer et al. (J. Agric. Food Chem. 1999, Vol. 47, pages 4611 –4620).

Lederer et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, of record). The use of the descriptive term "pharmaceutical composition" is deemed to be an intended use and hence does not constitute a claim limitation. Moreover, Lederer et al. disclose that the disclosed compositions are being tested in biological systems (see page 4619) that would necessarily require them to be acceptable for administration to a subject.

Lederer et al. differ from the instant invention in that the disclosed 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 is not disclosed to be at least 95% pure (i.e. the disclosed composition contains two regioisomers – see page 4615).

It would have been obvious for one of ordinary skill in the art to separate the regioisomers in order to fully characterize them.

One would have had a reasonable expectation of success as the methods used for the separation of regioisomers are well known in the art.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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ROBERT A. ZEMAN
PRIMARY EXAMINER

April 26, 2007